

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA
ex rel. Brook Jackson,

Plaintiff,

v.

VENTAVIA RESEARCH GROUP, LLC;
PFIZER INC.; ICON PLC,

Defendants.

CASE NO. 1:21-CV-00008-MJT

VENTAVIA RESEARCH GROUP, LLC'S MOTION
TO DISMISS AND BRIEF IN SUPPORT

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Defendant Ventavia Research Group, LLC hereby moves to dismiss Relator Brook Jackson's Amended Complaint (Dkt. 17, or the "Complaint").

INTRODUCTION AND STATEMENT OF ISSUES

The defendants in this case were part of a modern miracle: the rapid development of a life-saving vaccine for a novel coronavirus during a raging pandemic. This extraordinary achievement required unprecedented effort from countless individuals, including the need to conduct clinical vaccine trials at hundreds of test sites as quickly and safely as possible. Relator worked for one testing contractor for 18 days, and she now says that contractor didn't perfectly follow Pfizer's trial protocols for every trial participant. Relator then extrapolates from those alleged violations—while admitting she was only exposed to a few patients from trial sites that represented a tiny sliver of the overall Phase 3 trial (.03%, per Relator's overstated allegations)—to allege a far-reaching theory that the United States was wholly defrauded in its purchase of Pfizer's COVID-19 vaccines.

But the government doesn't think it was defrauded. It has known about these alleged shortcomings for nearly two years and says it would have bought the vaccines anyway. Indeed, the government has continued to approve and purchase Pfizer's vaccine—because it saves lives. The government also declined to join this misguided litigation. Because Relator purports to bring her claims on behalf of a government that doesn't think they are meritorious, the case should be over. But Relator's claims fail for several other independent reasons as well. The False Claims Act ("FCA") is supposed to be a tool for rooting out government fraud, not amplifying a publicity-seeking smear campaign. Relator's complaint should be dismissed, in full, with prejudice.

When the infectious disease now known as COVID-19 took hold of the world in early 2020, leaders across the globe scrambled to combat the pandemic by any possible means. On May 15,

2020, President Donald J. Trump announced Operation Warp Speed, a joint initiative led by the Department of Health and Human Services and the Department of Defense that was aimed at accelerating the private development of a COVID-19 vaccine by January 2021. This initiative charged the world's most foremost medical experts, pharmaceutical companies, and clinical trial specialists with an audacious goal: develop a safe, effective vaccine to a novel, deadly disease in six months. Pfizer and others in the medical and pharmaceutical communities answered the call and quickly identified several promising vaccines. These private companies then turned to clinical trial specialists to test those vaccines in massive, privately funded trials. Ventavia is a leading clinical research firm, specializing in trials of pediatric, maternal, and adult vaccines and other medicines. So naturally, Pfizer enlisted Ventavia and others to help conduct the COVID-19 vaccine trials.

Ventavia hired a number of new employees to handle the additional workload related to these trials and to keep up with its existing workload. Relator was one of those new hires. Almost as soon as she got to Ventavia, however, it was clear that Relator came with an agenda. Within days of her hiring, Relator began secretly recording conversations with other employees and trying to get them to say negative things about the company. Though Relator did not yet have a key to access the building (because she refused to sign the employee handbook), she would wait until all employees left for the day, access confidential and protected areas, and take pictures of those areas on her personal cell phone (even though she had a company phone). Relator stole hundreds of company documents during her nightly excursions, documents she has since leaked to the media and the public. She violated company policies, failed to complete required training on the trial protocol, disregarded patient privacy, unblinded herself and others on the clinical trial, and displayed an alarming level of disrespect towards the company, its patients, and its employees—

all of which led to Ventavia terminating her for cause after 18 days on the job.

Relator now makes herself out to be a watchdog for concerns about Ventavia’s compliance with Pfizer’s extensive clinical trial protocols. Yet while she was employed, Relator made only vague insinuations about the conduct of the trial and refused to comply with specific requests from her management to detail and document her alleged concerns so that they could be addressed. Relator never tried to solve any of these so-called problems. She focused instead on gathering confidential information that she is now using to spread misinformation about Ventavia, Pfizer, and the United States government itself. Despite working for Ventavia for less than three weeks, Relator has flooded the internet and the airwaves with sweeping allegations that seek to impugn the entire multi-year effort to develop and test the vaccine. After she was terminated, Relator initiated a media smear campaign against all of the above, leaking confidential information and documents to the media and even creating a self-promotional website and Twitter account where she posts the confidential information herself and raises funds to support her litigation efforts.

Relator then filed this baseless FCA suit on behalf of the United States, though she has publicly and repeatedly declared that the government is “complicit” in the alleged fraud and is attempting to hide the truth about Pfizer’s COVID-19 vaccine. This is a flagrant misuse of the FCA, which is designed to recover funds that the government improperly paid on false premises. Relator is instead using the FCA to build a personal brand and harass key contributors to the continued development of COVID-19 vaccines that have saved millions of lives and appear to be bringing the pandemic to an end. Relator’s allegations fail to state any claim for FCA liability—and Counts I & II of the Complaint should be dismissed—for several independent reasons.

First, Relator has not sufficiently alleged the details of *any* “false” claims for payment to

the United States government. The FCA is not a tool for generalized enforcement of federal law; its provisions apply only where the defendant submits materially false claims for payment to the government. So, FCA liability attaches not to the underlying misconduct, but to the claim for government payment. Yet Relator focuses almost exclusively on Ventavia’s alleged violations of the clinical trial protocols and says little about any claims for payment from the government. The only such claims alleged here are the payments that Pfizer allegedly received from the Department of Defense for the vaccines themselves. But Relator has *zero* details about the content, context, or timing of those alleged invoices—because she never worked for Pfizer. Without those details, Relator cannot sufficiently allege how or why (or whether) those claims were false, meaning she cannot state a claim for FCA violations under well-settled law in the Fifth Circuit. And Pfizer’s Motion to Dismiss (Dkt. 37) shows that Relator’s allegations of falsity are wrong in many respects.

Second, even if Relator could show that the alleged protocol violations rendered some claims for government payment false, her lawsuit would still fail because the alleged violations were immaterial to the government’s payment decisions. A “material” falsehood is one that would have caused the government to deny the disputed payment; if the falsehood wasn’t material, the FCA wasn’t violated. And that’s precisely the case here because the government has continued to approve and purchase the Pfizer vaccine after learning about Relator’s allegations about Ventavia’s trials. Indeed, the FDA has said these alleged violations wouldn’t have made a difference. That makes sense, of course, because the Ventavia trial participants represented such a small piece of the overall clinical trials and because the vaccine was proven safe and effective in tens of thousands of other trial participants—not to mention millions of people who have been protected since. The alleged violations here were immaterial as a matter of law and cannot support a viable FCA claim.

Third, Relator has not sufficiently alleged (because she cannot) that Ventavia itself violated the FCA—meaning the claims against Ventavia must be dismissed at a minimum. Again, FCA liability attaches only to false claims for government payment. Relator never attempts to allege that Ventavia itself demanded or received government payment (because it didn’t). So, Relator must rely on indirect theories of liability under the FCA, alleging that Ventavia caused Pfizer to present false claims to the government or that Ventavia made or used false records or statements that caused the submission of false claims. But to clear the causal gap required by these theories, Relator must show some affirmative act on Ventavia’s part that was a substantial factor in inducing Pfizer to submit claims for government payment. Her allegations don’t even get close: other than a few conclusory recitations of the statutory language (which fall short under *Twombly* and *Iqbal*), Relator offers nothing to show that Ventavia caused—or even knew about—any false claims for government payment. Counts I & II must be dismissed as to Ventavia for this additional reason.

Relator also seeks damages under the FCA’s retaliation provision in Count III, alleging that she was terminated for raising concerns about Ventavia’s protocol compliance, but this claim fares no better. While the fundamental allegation here is false as a matter of fact—Relator was fired for violating company policy and patient confidentiality, not for raising red flags about the clinical trial—the retaliation claim fails even the most basic pleading burden. The FCA’s retaliation provision applies only when the relator has engaged in protected activity by reporting concerns about government fraud, not just about regulatory violations. Yet Relator only claims that she did the latter. Nor does she allege that Ventavia *knew* she was concerned about government fraud. Both deficiencies are independently fatal to her claim for FCA retaliation.

For these and other reasons, Relator fails to state any claim for relief against Ventavia, and her Complaint should be dismissed under Rule 12(b)(6). In the alternative, the Court can dismiss the Complaint as a sanction for Relator’s willful violation of the FCA’s sealing requirement.

LEGAL STANDARDS

The False Claims Act, 31 U.S.C. §§ 3729-3733, prohibits the knowing submission of materially false claims for payment to the government. As part of its enforcement scheme, the FCA permits private parties (called *qui tam* relators) to file suit on behalf of the United States. *United States ex rel. Spicer v. Westbrook*, 751 F.3d 354, 364 (5th Cir. 2014). To state a claim for relief under the FCA, the relator must allege: (1) a false statement or fraudulent course of conduct; (2) that was carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money, *i.e.*, that involved a “claim” for payment. *Id.* at 365 (citation omitted).

Given its punitive character, “[t]he False Claims Act is not ‘an all-purpose antifraud statute’” or a vehicle for punishing “garden-variety” regulatory violations. *Universal Health Servs. Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 194 (2016) (quoting *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 672 (2008)). So, it is not enough for a relator to allege merely that a defendant violated a contract provision, statute, or regulation. *United States ex rel. Steury v. Cardinal Health, Inc.*, 625 F.3d 262, 268 (5th Cir. 2010). In cases like this one where the FCA claim turns on alleged violations of such a requirement, FCA liability only exists where the defendant submits a claim for payment to the government knowing that a contractual, statutory, or regulatory violation rendered the claim materially false. *See Escobar*, 579 U.S. at 186-87; *see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997) (the heart of an FCA claim is a “material misrepresentation[] made to qualify for government privileges or

services” or payment) (quotations omitted). A successful claim in these cases “often hinges on whether the false claim was ‘material,’” *i.e.*, whether the government would have paid the claim if it knew about the statutory or regulatory violation. *United States ex rel. McLain v. Fluor Enters., Inc.*, 681 F. App’x 355, 360 (5th Cir. 2017). This “rigorous” materiality rule is strictly enforced to avoid turning every federal law violation into an FCA claim. *Escobar*, 579 U.S. at 192-94.

Like any other complaint in federal court, FCA complaints must be supported by plausible facts, not empty conclusions. Rule 8(a) requires a plaintiff to “provide the grounds of his entitlement to relief [with] more than labels and conclusions” or a “formulaic recitation of the elements.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007) (internal alterations omitted). “Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Instead, “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Id.* (quoting *Twombly*, 550 U.S. at 570). “‘A complaint must fail if it offers only naked assertions devoid of further factual enhancement.’” *Sinclair v. Petco Animal Supplies Stores, Inc.*, 581 F. App’x 369, 370 (5th Cir. 2014) (quotation omitted).

FCA claims must also meet the heightened standard of Rule 9(b). *United States ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App’x 890, 894 (5th Cir. 2013). Rule 9(b) requires “specificity as to the statements (or omissions) considered to be fraudulent, the speaker, when and why the statements were made, and an explanation of why they were fraudulent.” *United States ex rel. Edgett v. Kimberly-Clark Corp.*, No. 3:15-cv-00434-B, 2017 WL 4222697, at *3 (N.D. Tex. Sep. 22, 2017) (quotation omitted). In other words, the relator must state “the who, what, when, and where” of the alleged false claims. *United States ex rel. Integra Med Analytics LLC v. Baylor Scott &*

White Health, 816 F. App'x 892, 896-97 (5th Cir. 2020). The Fifth Circuit applies Rule 9(b) to FCA claims “with bite and without apology.” *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 F. App'x 237, 240 (5th Cir. 2020) (quotation omitted).

ARGUMENTS AND AUTHORITIES

I. Counts I and II should be dismissed because Relator fails to state a claim for any violations of the False Claims Act.

Relator alleges in Counts I and II that, in essence, the defendants violated the FCA because Ventavia did not comply with all of the requirements in Pfizer’s clinical trial protocol. (*See, e.g.*, Complaint ¶¶ 274-278.) These counts fail to state any claim for relief against Ventavia or anyone else—and should be dismissed with prejudice—for several independent reasons.

A. Relator fails to sufficiently allege the details of any false claims for payment to the government.

Initially, Relator falls short in alleging the details of *any* false claims for government payment. The Complaint should be dismissed as to all defendants for this reason alone.

Proof of a “false claim against the government is the ‘*sine qua non*’ of liability under the FCA.” *United States ex rel. King v. Solvay Pharms., Inc.*, 871 F.3d 318, 326 (5th Cir. 2017) (quoting *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009)). That is because the FCA attaches liability not to the underlying misconduct, but to the *claim* for payment. *United States ex rel. Longhi v. United States*, 575 F.3d 458, 467 (5th Cir. 2009). Since this is the linchpin of an FCA claim, this Court and others require the relator to plead the details of the alleged false claim, including “the time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what that person obtained thereby.” *United States ex rel. Reddell v. DynCorp Int’l, LLC*, No. 1:14-cv-86, 2019 WL 12875471, at *4 (E.D. Tex. Mar. 20, 2019)

(quotation and alteration omitted); *United States ex rel. Wismer v. Branch Banking & Tr. Co.*, No. 3:12-cv-1894-B, 2013 WL 5989312, at *3 (N.D. Tex. Nov. 12, 2013).

Relator can't clear this hurdle because the Complaint does not allege any factual details showing that Ventavia—or anyone else for that matter—“actually submitted” a false claim to the government for payment. *Wismer*, 2013 WL 5989312, at *3; *Nunnally*, 519 F. App'x at 890, 894 (affirming dismissal because complaint “does not identify a single claim submitted by [defendant] for services rendered pursuant to an illegal referral, let alone one for which [defendant] expressly certified its compliance with federal law”). Again, the focus here is on the claim for payment, not on the alleged violations of regulatory requirements. Relator tries to mask her shortcomings on this element behind pages of general regulatory background (nearly half the complaint) and countless alleged violations of the Pfizer testing protocol, no matter how minor or disconnected from the government (*e.g.*, the improper disposal of used needles (Complaint ¶ 244)).

The only claims for government payment that Relator alleges are the monthly invoices she says that Pfizer sent to the Department of Defense seeking payment for doses of the life-saving COVID-19 vaccine. (Complaint ¶¶ 133-139.) But Relator does not apparently have any examples of these alleged invoices and therefore cannot allege any of the necessary details. Defendants and the Court are therefore left with no idea *who* presented the invoices to the government, *when* they did so, and—perhaps most importantly—*what* those invoices said. Courts have dismissed complaints with more detail. *See, e.g., United States ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 716-17 (N.D. Tex. 2011) (dismissing where complaint provided some patient initials, dates, and medical information, but failed to identify any individuals who participated in the alleged fraud or made false statements with the requisite intent); *see also Wismer*, 2013 WL 5989312, at *5

(dismissing complaint that “fails to identify the ‘specific actions of specific individuals at specific times that would constitute’ false claims actually submitted to the Government”).

Because of these pleading deficiencies, it’s hard to tell what Relator thinks the false statements were here. Relator’s theory appears to be based on an allegedly false certification of compliance with all relevant laws, which creates its own set of problems. (*E.g.*, Complaint ¶ 143.) But Relator lacks even the specific details to allege what exactly was certified—she just vaguely suggests that Defendants must have certified something like the language she found in a federal regulation. (*Id.*) Without knowing what precise certifications are at issue, how are Defendants supposed to defend themselves? *United States ex rel. Smart v. Christus Health*, 626 F. Supp. 2d 647, 656-57 (S.D. Tex. 2009) (dismissing complaint where relator failed to identify “when Defendants falsified certifications and what the contents of those certifications were”). Defendants are entitled to more specificity than that in pleadings that threaten to ruin their reputation and impose treble damages. *See Nunnally*, 519 F. App’x at 892 n.2 (“The heightened pleading standard for fraud claims supplies defendants with the information they need to prepare responses, prevents discovery intended as a mere fishing expedition, and protects the defendants’ reputations from baseless allegations.”); *Wall*, 778 F. Supp.2d at 717 (“Defendants are entitled to a pleading which specifies the manner in which [defendant] allegedly instructed its employees to falsify certifications for specific individual patients [and] that those employees did so with the requisite intent.”).¹

Of course, it is no surprise that Relator doesn’t have the details of the alleged false claims here: she didn’t work for Pfizer at all, and she only worked for Ventavia for 18 days. She is not a

¹ Moreover, as Pfizer explains in its Motion to Dismiss (Dkt. 37), Relator’s false certification theory fails as a matter of law for several independent reasons. Ventavia hereby incorporates by reference Section I of Pfizer’s Motion and seeks dismissal on those additional grounds. (Dkt. 37 at 20-25.)

whistleblowing insider; she's a rabble-rousing outsider. The purpose of the FCA's *qui tam* provisions is to encourage insiders with knowledge of government fraud to blow the whistle. *See* H.R. Rep. No. 99-660 at 22-23 (1986); 31 U.S.C. § 3730(b)(1). Relator has no such knowledge. She has observations about the conduct of the trial at a couple test sites from her 18 days of employment with Ventavia (which she appears to have specifically sought out with the goal of publicly smearing Defendants), with no factual support for how those alleged violations are connected to the submission of claims or the government's payment decisions. As part of her ongoing publicity tour, Relator uses these same generalized and vague allegations to discredit the vaccine itself (and proudly posts the interviews to her website—www.iambrookjackson.com). But in so doing, she's all but conceded that she lacks the details to allege false claims for government payment.

Without those details, Relator must depend on the *Grubbs* exception to survive dismissal. In *Grubbs*, the Fifth Circuit held that a complaint *may* survive a pleading challenge if a relator is unable to include all the details of an actually submitted false claim, but only where relator alleges "particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." 565 F.3d at 190. The relator in *Grubbs* had done just that: he alleged particularized, first-hand knowledge of a fraudulent scheme, including details such as the date, place, and participants in a dinner meeting at which several physicians actually tried to recruit the relator to participate in the scheme. *Id.* at 191-92. That relator also alleged in detail how nursing staff tried to help him record visits that hadn't occurred. *Id.* at 192.

Relator's allegations don't get close to that, and she doesn't try to allege the particular details of a scheme to submit false claims. As mentioned above, Relator includes mounds of allegations about so-called regulatory violations, but nothing about a fraudulent scheme and not

much beyond the same few conclusory statements repeated throughout (*e.g.*, “Defendants’ fraudulent schemes transform these certifications into false certifications...” (Complaint ¶ 279)). The only things Relator attempts to describe in detail are alleged regulatory violations, improper training, improper storage, etc. Because Relator does nothing to connect those allegations to any scheme to submit false claims, “the holding in *Grubbs* is unavailing to salvage [her] Complaint.” *Wismer*, 2013 WL 5989312, at *5; *United States ex rel. Jamison v. Career Opportunities, Inc.*, No. 3:16-CV-3248-S, 2019 WL 460229, at *8 (N.D. Tex. Feb. 6, 2019). Allowing Relator’s baseless claims to go forward would lead to exactly the type of fishing expedition that Rule 9(b) is intended to prevent. This Court and others routinely dismiss FCA claims for failing to plead the “who, what, when, where, and how” of a false claim to the government.² The Court should do the same here.

B. Any false claims were immaterial to the government’s payment decisions.

Yet even if Relator could cobble together the details of some false claims and overcome Pfizer’s independently fatal arguments about her false certification theory, dismissal would still be required for a more straightforward (and unavoidable) reason: any false claims about Ventavia’s clinical trials were immaterial to the government’s payment decisions. FCA cases “often hinge[] on whether the false claim was ‘material,’” and this case is no different. *McLain*, 681 F. App’x at 360. Relator cannot allege materially false claims—and thus, cannot establish any FCA violation—because Ventavia’s alleged violations of the clinical trial protocols had no effect on the government’s decision to purchase Pfizer’s life-saving COVID-19 vaccines.

² *United States ex rel. Woodard v. DaVita, Inc.*, No. 1:05-CV-227, 2011 WL 13196556, at *3 (E.D. Tex. May 9, 2011); *Wall*, 778 F. Supp. 2d at 719; *United States ex rel. Bennett v. Medtronic, Inc.*, 747 F. Supp. 2d 745, 785 (S.D. Tex. 2010); *United States ex rel. DeKort v. Integrated Coast Guard Sys.*, 705 F. Supp. 2d 519, 538, 544 (N.D. Tex. 2010).

The materiality test asks whether the alleged falsity had a “natural tendency to influence” the government’s payment decision—in short, would the government have paid the claim if it knew the relevant statements were false? *See United States ex rel. Patel v. Catholic Health Initiatives*, 792 F. App’x 296, 301 (5th Cir. 2019). “The materiality standard is demanding,” and is not satisfied by “garden-variety breaches of contract or regulatory violations.” *Escobar*, 579 U.S. at 194. Nor is a violation material just because the government “would have the option to decline to pay” if it knew of the noncompliance. *Id.*; *see also Porter*, 810 F. App’x at 241. The materiality test looks instead to the statement’s “effect on the likely *or actual* behavior” of the government. *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 661 (5th Cir. 2017). So, “*if the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated*, that is very strong evidence that those requirements are not material.” *Escobar*, 579 U.S. at 195 (emphasis added). *Escobar* “hammered home the ‘rigorous’ nature of” the FCA’s materiality element, making it fertile ground for dismissal. *Harman*, 872 F.3d at 662.

Relator cannot clear this bar because Ventavia’s alleged violations of the testing protocol would not have made a difference to the government’s payment decisions: the Department of Defense would have purchased the Pfizer vaccines regardless. We know that because the government has said so explicitly and because it has continued to purchase Pfizer vaccines long after learning about Ventavia’s alleged protocol violations. *Escobar*, 579 U.S. at 195. And Relator can’t dispute that the government has paid Pfizer’s claims in full despite knowing about potential violations of the testing protocol—because she alleged as much in her Complaint (*see ¶¶ 262, 266*) and on her public Twitter page, proclaiming to anyone who will listen that she reported Ventavia’s alleged violations to the government as early as September 2020. Below are just a few examples:

Brook Jackson 🌈 💜
@IamBrookJackson

...

2. It is important to note that I reported my concerns to FDA in late September 2020. At that time, there were about one thousand enrolled; however, Ventavia continued to enroll subjects after this date, so I anticipate the final number to be significantly higher.

12:12 AM · Nov 10, 2021 · Twitter Web App

2 Likes

Brook Jackson 🌈 💜
@IamBrookJackson

...

REMINDER: FDA OIG DOD DOJ HHS & others knew about Pfizer's clinical trial since Sep 2020! Safety efficacy criminal misconduct & they took no action. Pfizer knows! Tell the people how you sent your big shot attorney, Mark to intimidate me. Tell them how you got my cell #.

10:46 PM · Jan 20, 2022 · Twitter for iPhone

21 Retweets 1 Quote Tweet 60 Likes

Brook Jackson 🌈 💜
@IamBrookJackson

...

Replies to @_ShotaManDown @US_FDA and @pfizer

The FDA & US govt knew about the Ventavia data and are complicit in fraud, period. There is no question or any way to cover that up.

My question is: When will Pfizer and those involved be held accountable? They need to answer for what they've done.

3:32 PM · Feb 13, 2022 · Twitter for iPhone

75 Retweets 3 Quote Tweets 245 Likes

(App.1; App.2; App.3.)³ Relator even publicly posted the letters she says she sent to the FDA and Department of Defense reporting the concerns at the heart of her complaint. (App.4, 5.)

Yet despite knowing about these alleged violations, the FDA continued to approve—and the DoD continued to purchase—Pfizer vaccines.⁴ More than that, the FDA has made it clear that the alleged protocol violations would have made no difference to its approval decision. Following the public disclosure of Relator’s allegations in a piece published by an online news outlet, the FDA issued a statement confirming that it “has full confidence in the data that were used to support the Pfizer-BioNtech COVID-19 Vaccine authorization,” and it has maintained its authorization of the Pfizer vaccine to this day. (App.6.) Perhaps the purest articulation of the materiality defect here comes from Relator’s former attorney (in an attorney-client communication that Relator posted on her website): “The government has told us that the FDA was aware of misconduct by Ventavia and would have approved the vaccine even if they had known about it.” (App.7.)⁵

³ In evaluating a motion to dismiss, this Court may consider the allegations in the Complaint and other documents that are: (1) incorporated in the Complaint; (2) central to the claims in the Complaint; or (3) subject to judicial notice, including matters of public record and websites. *See, e.g., Hicks v. Lingle*, 370 F. App’x 497, 498 (5th Cir. 2010) (per curiam); *Brooks v. United Dev. Funding III, L.P.*, No. 4:20-cv-00150-O, 2020 WL 6132230, at *33-34 (N.D. Tex. Apr. 15, 2020).

This Court can take judicial notice of the existence of Relator’s internet posts (if not their veracity), and Relator cannot reasonably challenge her own admissions. *See AGIS Software Dev. LLC v. Apple, Inc.*, No. 2:17-CV-00516-JRG, 2018 WL 2721826, at *4 (E.D. Tex. June 6, 2018). (*See also* Dkt. 37 at 16 n.19.) Alternatively, if the Court declines to take judicial notice of these materials, it could resolve the materiality argument by summary judgment based on the undisputed evidence showing the government was aware of the alleged protocol violations. FED. R. CIV. P. 12(d).

⁴ <https://www.defense.gov/News/Releases/Release/Article/2501947/biden-administration-purchases-additional-doses-of-covid-19-vaccines-from-pfizer/> (*See also* Dkt. 37 at 16 n.21.)

⁵ In the same email, Relator’s former lawyer suggests that the FDA’s knowledge doesn’t matter because the DoD purchased the vaccines. This distinction is meaningless. For one thing, Relator reported the alleged protocol violations to the DoD just as she did to the FDA. (App.5.) But even if that weren’t true, Relator’s theory sets up the FDA’s authorization as the defining event that resulted in DoD payments—so if the alleged violations are immaterial to the FDA’s authorization

That position makes sense, of course. Even taking Relator’s allegations at face value, the participants in Ventavia’s clinical trials represented *only .03% of Pfizer’s overall Phase 3 trial*—so the FDA had a lot of other trial data to go on. (Complaint ¶ 80.)⁶ The government’s position also makes sense because the Pfizer vaccine has, in fact, saved countless lives in the last year and a half; the data is no longer theoretical. Because the government’s position on the approval and purchase of the Pfizer vaccine did not change after it learned about Relator’s allegations (and remains unchanged), any alleged protocol violations were immaterial as a matter of law.

The facts here are similar to those addressed by the Fifth Circuit in *United States ex rel. Porter v. Magnolia Health Plan, Inc.*, where the court affirmed the dismissal of an FCA complaint on materiality grounds. 810 F. App’x at 241-42. In doing so, the Fifth Circuit noted that the Mississippi Division of Medicaid “took no action” after learning of plaintiff’s allegations of fraud and instead “continued payment and renewed its contract with [the defendant] several times.” *Id.* at 242. Based on this clear evidence of continued government payment, the court held that plaintiff had not done enough to meet its “substantially increase[d]” burden on materiality. *Id.*

This case is no different. Indeed, Relator has not alleged any of the other materiality factors that might help clear this bar. *See Harman*, 872 F.3d at 665, 668 (holding that relator’s other evidence was insufficient to overcome the defendant’s essentially unrebutted evidence of continued government payment); *but see United States ex rel. Mitchell v. CIT Bank, N.A.*, No. 4:14-

(and they are), they are also immaterial to the DoD’s payment decisions. And the contract documents attached to Pfizer’s Motion confirm this connection. (Dkt. 37 at 13-14.)

⁶ And even this allegation is overstated. Relator claims Ventavia enrolled roughly 1,500 people out of 43,998, which amounts to only .03%. (Complaint ¶ 80.) In fact, Ventavia only enrolled 1,126 participants. Either way, there’s no dispute that the participants in Ventavia’s trials represented a minuscule portion of the overall Phase 3 trial.

CV-00833, 2022 WL 812364, at *13 (E.D. Tex. Mar. 16, 2022) (denying summary judgment on materiality grounds where other materiality factors created a fact issue). For one thing, the alleged certifications at the heart of Relator’s theory turn on “broad boilerplate language generally requiring a contractor to follow all laws, which is the same type of language *Escobar* found too general to support a FCA claim.” *Porter*, 810 F. App’x at 242 (quotations omitted). Relator likewise does not allege that the government designated each (or any) of Pfizer’s voluminous clinical trial protocols as “conditions of payment.” *Escobar*, 579 U.S. at 194.⁷ Nor does she allege that the government has ever declined payment to a vaccine manufacturer for similar reasons. *Escobar*, 579 U.S. at 195. While none of those factors would be sufficient to overcome the overwhelming evidence of the government’s continued payment decisions, their absence makes this an easy case. Relator can’t allege materiality, so she has not alleged any FCA violations.

Relator probably knows that. She appears more interested in making this case a referendum about what the government told the public about the development and testing of the COVID-19 vaccine. (*See* Dkt. 37 at 17; Dkt. 40 at 5.) Those allegations may (or may not) be a valuable conversation for the public square; but they are not the basis for an FCA claim—because the government doesn’t think it was defrauded. “Congress enacted the FCA to vindicate fraud on the federal government, not second guess decisions made by those empowered through the democratic process to shape public policy.” *Harman*, 872 F.3d at 668-69. Relator is certainly entitled to second guess her government, but that doesn’t mean she’s entitled to litigate claims on its behalf. “When the government, at appropriate levels, repeatedly concludes it has not been defrauded, it is not

⁷ Pfizer’s Motion demonstrates that they were *not* conditions of payment—because the only such condition was the delivery of an FDA-approved vaccine. (Dkt. 37 at 14.)

forgiving a found fraud—rather it is concluding that there was no fraud at all.” *Id.* at 670. Relator’s claims fail for lack of materiality.

C. Ventavia did not cause the submission of any false claims.

Relator has not stated a viable FCA claim against *any* defendant, and this case should be dismissed in its entirety. But if nothing else, Relator has not alleged that Ventavia itself violated the FCA—because Ventavia has virtually no connection to the government and therefore made no false claims for government payment, the “*sine qua non*” of liability under the FCA. *Solvay*, 871 F.3d at 326. At a minimum, then, the claims against Ventavia must be dismissed.

Relator doesn’t even attempt to allege that Ventavia directly submitted claims for payment to the government. Nor could she. The only defendant who allegedly submitted *any* claim for government payment was Pfizer (Complaint ¶¶ 138, 146), and those claims did not violate the FCA for the reasons discussed above and in Pfizer’s Motion to Dismiss (Dkt. 37). Ventavia is at least two levels removed from those claims and from the government in general: even taking Relator’s allegations at face value, Pfizer delegated management of the clinical trial to Icon, which then supervised hundreds of clinical trial sites including Ventavia’s. (Complaint ¶¶ 4-5.) Relator also admits that Pfizer’s clinical trials were privately funded, meaning Ventavia was paid from private funds, not the government fisc. (*Id.* ¶ 136.) Again, the FCA is a tool for recovering money that the government improperly paid on false premises, not for punishing alleged regulatory violations. *E.g., Harman*, 872 F.3d at 669 (purpose of FCA is “to protect public coffers”). Because Ventavia never received a penny of government money, Relator cannot allege a direct FCA violation.

So, to hold Ventavia liable under the FCA, Relator must necessarily rely on some sort of causal leap—by alleging that Ventavia caused Pfizer to present false claims to the government or that Ventavia made or used false records or statements that caused the submission of false claims.

See 31 U.S.C. §§ 3729(a)(1)(A), (B); *see also Solvay*, 871 F.3d at 328-29 (affirming summary judgment on these indirect theories for failure to show causation); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) (“[T]he appropriate focus of th[is] inquiry is on ‘the specific conduct of the person from whom the Government seeks to collect.’”). Although Relator generally alleges both of these theories against Ventavia (Complaint ¶¶ 274-288), she has not supported either with the necessary pleadings.

To clear the causal gap here, Relator must allege a “sufficient nexus between [Ventavia’s] conduct and the ultimate presentation of the allegedly false claim.” *United States ex rel. Colquitt v. Abbott Labs.*, No. 3:06-cv-01769, 2016 WL 80000, at *6 (N.D. Tex. Jan. 7, 2016). This proximate-causation standard “demands more than mere passive acquiescence in the presentation of the claim” by someone else. *Id.* at *7 (citing *Sikkenga*, 472 F.3d at 714-15). Rather, the relator must show some “affirmative act” on Ventavia’s part that was a substantial factor in inducing Pfizer to submit claims for government payment. *Sikkenga*, 472 F.3d at 714-15; *see also United States ex rel. Riley v. St. Luke’s Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) (“The FCA applies to anyone who knowingly assists in causing the government to pay claims grounded in fraud[.]”) (quotations and alterations omitted). This test “separates the wheat from the chaff, allowing FCA claims to proceed against parties who can fairly be said to have caused a claim to be presented to the government, while winnowing out those claims with only attenuated links between the defendants’ specific actions and the presentation of the false claim.” *Sikkenga*, 472 F.3d at 714.

Relator’s allegations against Ventavia fall well short of that standard, including because there were no false claims in the first place. (*See also* Dkt. 37 at 25-27.) At no point does Relator even try to allege that Ventavia “actually caused” Pfizer to submit false claims to the government.

See Solvay, 871 F.3d at 329. In fact, Relator does not allege that Ventavia knew Pfizer would be making claims for payment to the government. Ventavia knew the FDA would consider the trial data in determining whether to authorize the vaccine for emergency use, but Relator does not allege that Ventavia knew the government would directly purchase the vaccines or what Pfizer would say in requesting payment. The FCA is only implicated in the latter scenario. Relator certainly does not plead facts establishing any “affirmative acts” by Ventavia that assisted or encouraged Pfizer’s claims for payment to the government. At best, she posits a generalized connection between Ventavia’s test sites, the FDA’s review of testing data for thousands of other trial participants, the FDA’s approval of the Pfizer vaccine, and Pfizer’s decision to seek government payment. “Such a generalized daisy chain of causation does not meet the requirements of Rule 9(b).” *Sikkenga*, 472 F.3d at 728 n.34; *see also D’Agostino v. ev3, Inc.*, 845 F.3d 1, 7-10 (1st Cir. 2016) (relator could not establish “causal link” between defendant’s alleged misrepresentations to get FDA approval for its medical device and the submission of claims to CMS by healthcare providers).

Moreover, to the extent Relator tries to articulate her claims under these causation-leaping theories, her allegations are far too conclusory to state a claim. She generally alleges that Defendants “caused the presentment” of false claims (Complaint ¶¶ 274, 281) and that Defendants made or used false records or statements to cause false claims to be paid (*id.* ¶ 284). But these are precisely the kinds of formulaic and conclusory allegations that are prohibited by *Twombly* and *Iqbal*. *E.g., Sinclair*, 581 F. App’x at 371. Relator also fails to give the particularized details necessary to satisfy Rule 9(b) for these indirect theories, including because she fails to allege specific facts regarding *what* the relevant false records and statements were, *who* made those records or statements, *when* they were submitted to the government, or *how* they were material in

causing the submission or payment of false claims. *Wismer*, 2013 WL 5989312, at *3. Finally, these allegations (like many others) improperly lump all Defendants together without segregating the alleged wrongdoing—which means they fail as to all defendants. *See, e.g., United States ex rel. Park v. Legacy Heart Care, LLC*, No. 3:16-CV-803-S, 2018 WL 5313884, at *6 (N.D. Tex. Oct. 26, 2018).

For all of those reasons, Relator has not sufficiently alleged that Ventavia caused the submission of false claims or made or used records or statements that caused the submission of false claims. Dismissal is required as to Ventavia if nothing else.

II. Count III should be dismissed because Relator fails to state a claim for FCA retaliation.

In the final section of her complaint, Relator alleges retaliation under 31 U.S.C. § 3730(h). To recover under this provision, Relator must plead and prove that: (1) she was engaged in protected activity while trying to stop an FCA violation, (2) her employer knew that she was engaged in protected activity, and (3) she was discharged or discriminated against because of the protected activity. *See, e.g., Thomas v. ITT Educ. Servs., Inc.*, 517 F. App’x 259, 262 (5th Cir. 2013); *United States ex rel. Patton v. Shaw Servs., L.L.C.*, 418 F. App’x 366, 371-72 & n.5 (5th Cir. 2011); *Robertson v. Bell Helicopter Textron, Inc.*, 32 F.3d 948, 951 (5th Cir. 1994). Relator’s retaliation theory fails for at least two independent reasons.

First, Relator does not sufficiently allege that she was engaged in “protected activity” under the FCA before she was fired. Not all complaints or reports of alleged misconduct are protected under this provision. *See Patton*, 418 F. App’x at 371-72; *Robertson*, 32 F.3d at 951. “For internal complaints to constitute protected activity in furtherance of a *qui tam* action, the complaints must concern false or fraudulent claims for payment submitted to the government.” *Patton*, 418 F. App’x at 372 (quotation omitted). Merely complaining to an employer about an

“improper” practice or even about “fraud” is not protected unless the complaint is that the employer is “defrauding the government.” *Id.*; *Hutchins v. Wilentz, Goldman & Spitzer*, 253 F.3d 176, 188 (3d Cir. 2001) (reporting “regulatory violations” is not a protected activity); *Robertson*, 32 F.3d at 950-52 (complaints about bills to government not protected activity where employee “never used the terms ‘illegal,’ ‘unlawful,’ or ‘qui tam action’”).

Relator’s alleged complaints here were on the wrong side of that line; at best, she says she reported regulatory violations before she was terminated, not government fraud (and even the misconduct she alleges didn’t violate federal regulations for reasons explained in Pfizer’s Motion to Dismiss). Relator says that beginning September 8, 2020—the day she began her employment at Ventavia—she reported “on a near-daily basis” that “patient safety and the integrity of the Pfizer-BioNTech vaccine trial was at risk.” (Complaint ¶ 238.) She goes on to allege that she discussed “virtually all” of the protocol violations she witnessed with Ventavia management. (*Id.* ¶¶ 238-39.) She then says she recommended pausing trial enrollment based on these alleged concerns, which Ventavia ultimately did. (*See id.* ¶¶ 247-61.)

Even if all of that were true (and it’s not), Relator does not allege that she ever alerted Ventavia to potential fraud on the government. Rather, she alleges that she complained about violations of the clinical trial protocol. This is not “protected activity” under the FCA’s retaliation provision—because internal complaints about regulatory violations and complaints about defrauding the government are not the same thing. *See Patton*, 418 F. App’x at 372 (element not satisfied because nothing showed employee concerned about “defrauding the government”).

Another judge in this District enforced that distinction to find that complaints about billing practices—with no indication that the relator was attempting to expose fraud within the meaning

of the FCA or to pursue, investigate, or assist in a *qui tam* action—did not rise to the level of protected activity. *United States ex rel. Reddell v. DynCorp Int'l, LLC*, No. 1:14-cv-86, 2019 WL 12875471, at *16 (E.D. Tex. Mar. 20, 2019). The court correctly held that the FCA’s retaliation provision only protects an employee who “intends to file such an action [under the FCA] and informs management clearly of that intention.” *Id.* (internal quotations omitted). Here, Relator merely alleges some internal criticism of protocol violations and safety risks, “without any indication that [she] was attempting to expose illegality or fraud within the meaning of the FCA.” *See id.* (internal quotations omitted). Her retaliation claim fails for this reason alone.

Second, Relator does not sufficiently allege that Ventavia *knew* she was engaged in protected activity. To satisfy this element, Relator must allege that Ventavia was aware she was investigating fraud against the government or that a *qui tam* action was a distinct possibility. *See Patton*, 418 F. App’x at 372; *Robertson*, 32 F.3d at 951-52. Relator does neither. In fact, Relator didn’t even bother to include a conclusory allegation that Ventavia knew she was engaged in protected activity, likely because it wasn’t (and she wasn’t). Her only allegations regarding Ventavia’s knowledge come when she lists all of the protocol and safety violations she says she reported to Ventavia during her 18-day employment, all of which she believed was within her duty to report as a Regional Director. (*See* Complaint ¶¶ 234-35, 238.) *None* of these internal complaints put Ventavia on notice that Relator intended “to pursue, investigate, or assist in a *qui tam* action,” as required, nor does Relator allege as much. *See Reddell*, 2019 WL 12875471, at *16.

Relator’s alleged reports to the FDA don’t help her retaliation claim either. (*See* Complaint ¶¶ 262-63.) Those allegations again suggest she was reporting regulatory violations at best, not fraud on the government. (*Id.* ¶ 262 (“On the following morning, Relator called the FDA’s hotline

to report *the clinical trial protocol violations and patient safety concerns* she witnessed.” (emphasis added).) But even if it were the latter, Relator does not allege that Ventavia knew about her reports to the FDA (and it did not, as a matter of fact). There can be no retaliation under the FCA if the employer did not know about the protected activity prior to the termination, and Ventavia did not. Count III should be dismissed as well.

III. Alternatively, Relator’s claims should be dismissed as a sanction for her willful, bad-faith violations of the FCA’s seal requirement.

For the reasons discussed above, Relator has no viable claim for relief and the Complaint should be dismissed on the merits. Indeed, given Relator’s public campaign to attack the defendants, the government, and the vaccine itself, a merits dismissal is in the public interest—to make clear that Relator’s dangerous allegations have no basis in law or fact. But, if the Court determines that some portion of the Complaint can survive Rule 12(b)(6), dismissal is nevertheless appropriate as a sanction for Relator’s willful violations of the FCA’s initial sealing requirement.

The FCA mandates that lawsuits filed by relators shall be initially “filed in camera, shall remain under seal for at least 60 days, and shall not be served on the defendant until the court so orders.” 31 U.S.C. § 3730(b)(2); *see also State Farm Fire & Cas. Co. v. United States ex rel. Rigsby*, 580 U.S. 39, 137 S.Ct. 436, 442 (2016). This requirement serves several fundamental purposes: ““(1) to permit the United States to determine whether it already was investigating the fraud allegations (either criminally or civilly); (2) to permit the United States to investigate the allegations to decide whether to intervene; (3) to prevent an alleged fraudster from being tipped off about an investigation; and, (4) to protect the reputation of a defendant in that the defendant is named in a fraud action brought in the name of the United States, but the United States has not yet decided whether to intervene.’” *Smith v. Clark/Smoot/Russell*, 796 F.3d 424, 430 (4th Cir.

2015) (citation omitted); *see also Rigsby*, 137 S.Ct. at 443 (“[T]he seal provision was meant to allay the Government’s concern that a relator filing a civil complaint would alert defendants to a pending federal criminal investigation.”).

When a relator violates the FCA’s seal provision—including by publicizing the existence of a still-sealed lawsuit—federal courts have statutory and inherent authority to dismiss the action with prejudice as a sanction. *See, e.g., Rigsby*, 137 S.Ct. at 444.⁸ Dismissal is not automatic, and not every seal breach justifies this admittedly harsh remedy. *United States ex rel. Rigsby v. State Farm Fire & Cas. Co.*, 794 F.3d 457, 471 (5th Cir. 2015). But dismissal is available as a sanction where the breach is egregious or where it imperils one of the fundamental purposes of the seal requirement. *See id.* at 471-72. The Fifth Circuit applies a three-factor balancing test to determine whether dismissal is warranted, considering: (1) the harm to the government from the violations; (2) the nature of the violations; and (3) whether the violations were done willfully or in bad faith. *Id.*

Those principles support dismissal here because there can be no dispute that Relator willfully violated the seal in January 2022 when she publicly posted the caption of the still-sealed case on her Twitter account, along with several allegations pulled directly from her still-sealed complaint. (Dkt. 40-1 at 87.) The case was not unsealed until February 10, 2022. (Dkt. 16.) And Relator has since admitted on her public website that she knew she wasn’t supposed to violate the seal, acknowledging that the court “ordered me to refrain from disclosing any information about the case” while it remained under seal and that her former lawyers warned her not to violate the seal. (Dkt. 40-1 at 6.) But, because she was frustrated about being “silenced,” Relator fired those

⁸ *See also, e.g., Smith*, 796 F.3d at 430; *United States ex rel. Summers v. LHC Grp., Inc.*, 623 F.3d 287, 296 (6th Cir. 2010); *United States ex rel. Lujan v. Hughes Aircraft Co.*, 67 F.3d 242, 247 (9th Cir. 1995); *United States ex rel. Pilon v. Martin Marietta Corp.*, 60 F.3d 995, 998-99 (2d Cir. 1995).

lawyers, posted about the still-sealed case on Twitter, “took [her] evidence to” an online publication called the BMJ for an extensive exposé (published in November 2021), and “retained new council.” (*Id.*) Given Relator’s brazen admissions, it seems likely that discovery will reveal more violations of the sealing requirement (if discovery ever becomes necessary). But, the judicially noticeable information already in the record shows that Relator willfully violated the seal.

Those breaches were egregious and done in bad faith because they were specifically designed to “bring[] information forward to the public” (*id.*) at a time when Relator knew that federal law prohibited her from doing just that. *See Rigsby*, 794 F.3d at 472 (noting that if “[relators] themselves communicated the existence of the suit” in press interviews “we would conclude that they acted in bad faith”). Worse yet, the public disclosures were designed to smear the defendants’ reputations at a time when they had no forum in which to defend themselves—because they didn’t know a lawsuit had been filed. *See Smith*, 796 F.2d at 430 (suggesting a “public” seal breach is inherently harmful to a defendant’s reputation). And these breaches harmed the United States, both by tipping off the defendants to the existence of the investigation and by directly impugning the integrity of the government itself. *See Rigsby*, 137 S.Ct. at 443.

No lesser sanction than dismissal is appropriate. Attorney discipline isn’t available here (*see id.* at 444) because Relator is not a lawyer and because her former lawyers apparently counseled her *not* to violate the seal. Monetary penalties likely won’t be meaningful (*see id.*) because Relator will just turn to online fundraising to pay whatever penalties the Court imposes, as she has done for other costs of litigation here. (*See Dkt. 37 at 15 n.17.*) Any sanction that allows this lawsuit to continue will leave Relator with the thing she cares about most: a platform to broadcast her misguided allegations about Pfizer’s COVID vaccine. Because it seems clear that Relator’s desire

“to get the story out” (Dkt. 40 at 5) outweighs her respect for federal law,⁹ the Court can and should (if necessary) dismiss her Complaint as a sanction for her willful violations of the FCA’s sealing requirement.

CONCLUSION AND PRAYER

Ventavia respectfully requests that this Court grant its Motion and dismiss with prejudice all claims asserted against it in Relator’s Amended Complaint (Dkt. 17). Ventavia also requests that this Court grant any other relief to which it may be justly entitled.

Respectfully submitted,

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COUNSEL FOR VENTAVIA

⁹ Relator provided even more evidence of this attitude following the case management conference on May 27, 2022. Even though the Court repeatedly emphasized that the conference was being held “off the record,” Relator posted a tweet within hours that purported to recount certain views that she says the Court expressed during the conference. (App.8.) In Ventavia’s view, Relator’s recitation is misleading at best; but the Court knows better what it did and did not say at the conference. Regardless, this tweet confirms yet again that Relator cares more about public information than even the restrictions placed on her by the Court.

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing document was served upon all counsel of record on June 6, 2022, pursuant to the Court's ECF filing system and the Federal Rules of Civil Procedure.

/s/ Taryn M. McDonald
Taryn M. McDonald

INDEX OF EXHIBITS

<u>Ex.</u> ¹⁰	<u>Description</u>
	Declaration of Taryn M. McDonald
1	Tweet from Brook Jackson dated November 10, 2021
2	Tweet from Brook Jackson dated January 21, 2022
3	Tweet from Brook Jackson dated February 13, 2022
4	Email from Brook Jackson dated September 25, 2020
5	Letter from Rebecca L. Gibson dated December 14, 2020
6	Cheryl Clark, <i>Experts Blow Whistle on Alleged COVID Vaccine Whistleblower Claims</i> , MEDPAGE TODAY (November 5, 2021)
7	Email string dated March 2 – 3, 2021
8	Tweet from Brook Jackson dated May 27, 2022

¹⁰ Citations to documents in the Appendix are in the form of “App.[ex.#].”